R-MVST Cells for Treatment of Viral Infections

NCT05183490

Status	RECRUITING
Phase	Phase 1
Sponsor	Columbia University
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (3)

- Men and women ages 18 years or older of all ethnic groups will be eligible for the treatment
- Patients with history of HCT or SOT who demonstrate evidence of viral reactivation and/or infection manifesting as end-organ or systemic disease due to one or more of the following viruses: EBV, CMV, ADV or BK virus and suboptimal response to the standard of care therapy.
- Recurrent or Multiple Viral Infection. RVI defined as occurrence of more than one episode of reactivation that required intervention or symptomatic disease in recipient of allogeneic HCT that required standard of care treatment. MVI defined as more than one virus reactivating (defined by PCR positivity) or causing symptomatic systemic or end-organ disease. At least one of those viral reactivations required standard of care intervention. No standard of care therapy is defined for ADV and BK. Patients with multiple infections/reactivations will be eligible as long as at least one of those viral infections meet the criterium of "refractory".

Exclusion (14)

- Patients with other uncontrolled infections, except for CMV, EBV, ADV or BK. For bacterial infections, patients must be receiving definitive therapy and have no signs of progressing infection for 72 hours prior to the day of infusion. For fungal infections, patients must be receiving definitive systemic anti-fungal therapy and have no signs of progressing infection for 1 week prior to R-MVST infusion. Progressing infection is defined as hemodynamic instability attributable to sepsis or new symptoms, worsening physical signs or radiographic findings attributable to infection. Persisting fever without other signs or symptoms will not be interpreted as progressing infection
- Patients who receive corticosteroids at e 0.5mg/kg prednisone or equivalent.
- Patients who received anti-thymocyte globulin (ATG, Alemtuzumab (Campath), or other T-Cell immunosupressive monoclonal antibodies in the last 28 days.
- Patients who received methotrexate, or other antimetabolite-type immunosuppressants that are toxic to proliferating T cells in the last 7 days.
- Patients who received extracorporeal photopheresis within the last 28 days.

... and 9 more (see full listing online)

Locations (1 total)

Columbia University Irving Medical Center, New York, New York, United States